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COMMENTS AND CONTROVERSIES

The Value of Considering Cost, and the Cost of Not Considering Value

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During my residency, which was, alas, some time ago, an attending physician instructed me to order a large battery of tests. These seemed to me to be highly unlikely to affect patient management. I asked him if this was really the best thing to do, and noted that it didn't seem cost effective. He replied to me, with righteous indignation, that it was "…not our job to consider cost" and that "…none of my patients ever paid me to be cost effective." I thought this was wrong then; I know it is wrong now.

Whether there was ever justification for our wishful societal delusion that everything we do in health care, and especially cancer care, could and should be above consideration of cost, we are now recognizing, albeit all too slowly, that we can no longer afford this luxurious fantasy. As every drug, device, and intervention we might choose, or not, to use in the care of a patient has a specific and often substantial cost attached to it, we can no longer ignore nor can we blindly accept that cost and feel that it has no place in our medical decision making. To continue to do so would inevitably bankrupt our health care system and prevent us from ever being able to provide necessary quality care for all.

In this context, the terms value, value-based care, and high-value medicine have increasingly entered into our discussions. Often missing, however, in this developing discourse is a clear understanding of what these terms actually mean. Too often an ethereal, vague concept of value is invoked to obscure or avoid a frank consideration of the real, hard cost. A drug regimen that works well is valuable, but if it costs $300,000 per patient per year, as some of our newer regimens do, then I would argue a priori that it costs too much, and a diversion of the discussion away from this hard cost to a vague concept of value can serve as a distraction from confronting this harsh reality. Also lost, or at least underappreciated in these discussions, is that we will accomplish nothing as we confront cost, define value, and embrace high-value care unless we also define and eschew low-value care. This means identifying certain practices that we now perform that we will stop performing, because they offer insufficient value to our patients to justify their continued use.

If You Don't Know the Cost, You Can't Know the Value

Too often, fear and anxieties cloud our understanding of cost and value in medicine, particularly when it comes to oncology. To illustrate these concepts more clearly, consider a far more trivial, less emotionally charged example, but one I feel nevertheless both illustrates the point and adds considerably to my own quality of life: a good glass of wine. Say that I'm able to purchase a bottle of a wine that I like for $20. If I enjoy a glass and feel it is a good wine for the amount of money I've paid, then I've gotten a good value. If I'm then able to find that same wine for several dollars less, I've now gotten a better value. If, however, the next time I try to buy that wine I am unable to find it for less than $25, then I've gotten a lesser value; if on another day I'm forced to pay $30 for a bottle of that same wine, I've gotten terrible value. At some point, if the price continues to rise, I will make some other choice; I won't buy that wine. My point is this: the wine is the same each time. The *benefits*, in this case, the taste and the pleasure I derive from it, stay exactly the same, while the *value* varies considerably.

As trivial as the above example may be, the same concept is true for any value discussion; until we know the price of something, we cannot assess its value, be it a product, a service, or, to the point at hand, a drug. For any of these, as the price for any fixed degree of benefit increases, the value goes down, and, importantly, vice versa. Thus, value is not synonymous with benefit. Value is best thought of as a ratio between the favorable, or beneficial, aspects of something and the costs, the detrimental, or negative, aspects. When we consider a cancer drug, the benefits might be measured in improved overall survival, tumor shrinkage, or improvement in quality of life—these would be the positive aspects. The adverse effects or toxicities, inclusive of the financial toxicity, or cost, would be the negative aspects. Without knowing all of these factors, we cannot begin to intelligently discuss what value of the drug might be or whether its value warrants its use.

The Disconnect Between Value and Cost

In cancer care, we in the United States have set neither targets nor expectations for value, nor have we established limits as to how low we are willing to go before admitting that a low-value drug is too low value to use (or how high a price we are willing to pay for a truly highly effective drug). In a value-driven, functioning market, a drug maker would be incentivized to maximize potential value by striving through innovation to maximize effectiveness and minimize toxicity, because higher value would be compensated with a higher price. Failing to achieve this but wishing to market the drug nonetheless, a company could maintain value, and thus, its presence in a properly functioning market, by lowering the drug price. Evidence consistently shows, however, that the price of a new cancer drug in the United States is independent of value, and is largely dependent simply on the price of recently marketed cancer drugs.[1,2] Thus, in oncology, what we have is a seriously broken, highly dysfunctional market.

Perverse Incentives

Markets function properly when value is well defined and understood and prices reflect that value. If, on one hand, a price is too high for a given value, buyers won't buy, and market forces lower the price. Sellers, on the other hand, can command a higher price for something that works better, or has higher value, because buyers are willing to pay more for it. Markets become dysfunctional when perverse incentives encourage sellers to sell, and buyers to buy, items whose values do not justify their prices. If, for example, a buyer is buying with someone else's money, the normal incentive to seek good value is diminished. If, as happens when we are compensated on the basis of a fixed percentage of the price (eg, average sales price + 6%), the buyer who decides on the purchase benefits more from an expensive drug than from an inexpensive one, we have introduced a perverse, value-independent incentive to buy a high-priced drug. When we pay a similar price for both a drug that provides minimal benefit and one that provides a greater benefit, such as greater efficacy, lower toxicity, or a novel mechanism, we have introduced another perverse incentive, as it is harder, and therefore riskier, to make a highly effective drug or a drug that attacks a novel target. Companies are thus perversely incentivized to put more effort than a market would otherwise dictate into the continued development of drugs that seem marginally effective, and to develop "me too" drugs to claim a share of an existing market, rather than creating a new market with a truly new class of drug.

The Rules of the Game, and the Gaming of the Rules

A number of counterproductive laws and regulations stand in the way of our re-establishing a healthy and functional cancer drug market. The laws that prevent the US Food and Drug Administration (FDA) from considering price are clearly outdated. Current lobbying practices by the pharmaceutical industry cannot be blamed for the existence of such regulations, but they are likely central to the failure to update them. Among the most problematic of the laws, and one heavily supported by the pharmaceutical lobby, is the law that forbids Medicare from negotiating price. The result of this legislative morass is that the FDA must approve a drug without consideration of what it will cost, and Medicare must buy that drug without the ability to negotiate a cost commensurate with the value of the drug. Therefore, once the FDA approves a drug, Medicare—using taxpayer money—must buy that drug at any price the drug company chooses to set. Whereas Medicare, using external data and advice, determines reimbursement rates and chooses how much to pay for virtually all other medical costs, such as doctor fees and hospital services, drug prices are left exclusively in the hands of the pharmaceutical industry.

High Reward for High Risk?

A justification that is often put forward for the high cost of drugs is that drug development is risky, and that development costs must include coverage of the costs of attempted drugs that failed. This, however, is not how the rewarding of risk is supposed to work. High risk should be compensated by high reward *if* that risk bears fruit, but one can only expect a small percentage of high-risk endeavors to succeed—that is the definition of high risk. If, however, a company can expect to be compensated handsomely for taking a risk that succeeds, but can also expect to be insulated from loss when other high-risk investments fail, then there is really no risk at all. In fact, what this constitutes is an upfront societal bailout in which the companies are overincentivized to spend heavily on risky ventures with the assumption that all of these costs can and will be passed on to the purchasing public. In such cases, no risk is taken. The concept is not dissimilar to what occurred in the 2008 post facto bailouts of the financial industry. Bankers who were supposed to be rewarded for taking risks when they succeeded, but suffer the consequences of failure when they did not, took inordinate risk and failed; however, they succeeded in disseminating the actual risk to others, such that rather than suffering the losses, they received public funds to bail them out.

Such arrangements remove the incentives for prudent caution and encourage reckless risk taking. So, for example, with the new excitement in immuno-oncology, both larger drug companies, as well as numerous investment firms, are rushing to purchase smaller companies that have putative immunotherapeutic products in development. The immediate result of this purchasing frenzy of preclinical agents at exorbitant prices is a dramatic increase in the so-called cost of drug development when, in fact, it is an increase in the amount of money paid to the investment community for having sold unproven therapies to drug companies at dramatically inflated prices driven up by competitive bidding. What the costs will be if these development costs are passed on to the consuming public is a matter of grave concern.

What Needs to Happen

We need to understand, and we must help our patients, our partners in industry, and our elected officials to understand, the meaning and importance of value, and that there must be upper limits to cost. We must recognize, and then work to remove, the perverse incentives that impede the healthy functioning of the cancer drug market. We need to insist on rational updates to the laws and regulations that define the actions of the FDA and Centers for Medicare & Medicaid Services (and that create an artificial barrier between the two), resist the special interest lobbies, and refute the specious arguments that stand in the way of updating those laws. Ultimately, it is we, the doctors, who must guide the discussion of what is valuable enough to command a high price, and, more importantly, what is not; and what is worthwhile, and at what price. We accept that we must consider toxicities versus benefits in our clinical decision making. We need to accept that it is our responsibility to consider financial toxicity as well.

AUTHOR'S DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

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